

EXHIBIT 23

Drug Safety and Availability > FDA Statement on the Ranbaxy Atorv...

<http://www.fda.gov/Drugs/DrugSafety/ucm329951.htm>

Home Drugs Drug Safety and Availability

Drugs

FDA Statement on the Ranbaxy Atorvastatin Recall

En Español¹

Update: 11/30/2012

FDA is notifying the public that after reviewing additional information related to the Ranbaxy atorvastatin recall, FDA has determined that the possibility of adverse health problems related to the recalled atorvastatin is extremely low.

What patients should know

- Patients who have the recalled medicine can continue taking it unless directed otherwise by their physician or health care provider.
- To date, FDA hasn't received any reports of injury.
- The possibility of adverse health problems related to the recalled atorvastatin is extremely low.
- If patients experience any adverse events, they should contact their health care provider, and report to FDA's MedWatch program.
- Ranbaxy decided to stop making atorvastatin until the company has thoroughly investigated the cause of the contamination and remedied the problem.
- The recall does not include atorvastatin 80mg strength or any other Ranbaxy product.
- FDA will continue to oversee the recall process and work with Ranbaxy to resolve quality issues.
- The FDA does not anticipate a drug shortage. FDA is working with other atorvastatin manufacturers to avoid a drug shortage and is closely monitoring the situation.

[11/29/2012] On Nov. 9, 2012, Ranbaxy Pharmaceuticals informed its customers of a voluntary recall of certain lots of the company's 10mg, 20mg, and 40mg dosage strengths of atorvastatin tablets. The lots of atorvastatin, packaged in bottles of 90 and 500 tablets, are being recalled due to possible contamination with very small glass particles similar to the size of a grain of sand (less than 1 mm in size).

Due to this quality issue, Ranbaxy has decided to stop manufacturing atorvastatin until it has thoroughly investigated the cause of the glass particulates and remedied the problem. Based on the information from Ranbaxy and from the FDA's initial assessment, the possibility of adverse events related to the recalled product appear to be low, and if any adverse events are experienced, they would be temporary.

At this time, we have not received any reports of patient harm due to glass particulates that may be in the recalled product.

Consumers who are concerned that they may have received a recalled product should consult with their pharmacist where they bought the product to confirm whether they received a recalled product, should stop taking the product if it was recalled, and should consult with their pharmacist or physician about how to obtain an alternative product.

Americans expect and deserve safe, effective, and high quality medications. The FDA continues to evaluate information associated with this recall and will notify the public as new information becomes available. The agency will continue to oversee the recall process, and work with the Ranbaxy to resolve these pharmaceutical quality issues.

Atorvastatin is a widely used cholesterol lowering medication that is available from several

manufacturers. While there is no anticipated drug shortage for any of the affected lots or strengths, the FDA is proactively monitoring the situation for the possibility of a shortage. The FDA is working with other manufacturers of atorvastatin to ensure adequate market supply in order to avoid shortages of atorvastatin as a result of this ongoing recall.

If patients experience any adverse events, they should contact their health care provider. Health care professionals and consumers can also report adverse events to MedWatch, FDA's adverse event reporting program:

- Complete and submit the report online: www.fda.gov/MedWatch/report.htm², or
- Download form³ or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Recalled Products

Product	Lot Number	Pack Size	NDC #	Expiry Date
ATORVASTATIN Calcium Tablets 10mg x 90	2436144	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 10mg x 90	2436582	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 10mg x 90	2441567	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 10mg x 90	2441568	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2436731	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437381	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437940	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437942	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437945	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437947	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437952	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437953	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437960	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2440676	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2440677	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2440680	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2440681	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 500	2437956	500's Bottle	63304-829-05	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 500	2437957	500's Bottle	63304-829-05	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 500	2440675	500's Bottle	63304-829-05	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434265	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434266	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434824	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434826	90's Bottle	63304-829-90	31-Jul-14

ATORVASTATIN Calcium Tablets 40mg x 90	2434827	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434828	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434829	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434830	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434831	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2436580	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2436725	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2436727	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2436729	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437377	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437380	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437941	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437943	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437944	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437949	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437950	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437955	90's Bottle	63304-829-90	31-Aug-14

Related Information

- Questions and Answers on the Ranbaxy Atorvastatin Recall⁴

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1. /Drugs/DrugSafety/ucm330214.htm
2. <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

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3. [/Safety/MedWatch/HowToReport/DownloadForms/default.htm](#)

4. [/Drugs/DrugSafety/ucm329961.htm](#)